



The Wyoming Immunization Program Newsletter

A VISion of Excellence

By Jan Bloom

Recently I took my four-year-old son for a well child visit, during which time he received his kindergarten shots. At the time of the visit, the WyVIP provider did not provide any Vaccine Information Statements (VIS) to me about the immunizations my son was to receive. As an educated parent and consumer of healthcare services, I knew that I should have received a VIS for each shot given. Rather than point that fact out during the visit, I opted instead to use this experience as an opportunity to remind WyVIP providers to provide consumers with Vaccine Information Statements prior to vaccination.

As a reminder, federal law requires that VISs be disseminated **prior to** administration of vaccines covered by the National Childhood Vaccine Injury Act. For more information, please see the **INSERT** "It's Federal Law!".

The purpose of the VIS is to ensure that consumers are educated about the importance of and risks of vaccines given as well as how to monitor and treat a person who has been immunized. VISs are available in 29 different languages. To obtain the most current VIS, visit the CDC web site at http://www.cdc.gov/vaccines/Pubs/vis/default.htm.

It is critical that WyVIP providers ensure consumers have the opportunity to read the VIS or have it read to them prior to administration of vaccines and that they receive the most current VIS for each vaccine before it is administered.

Thank you for your attention to ensuring consumers receive the most accurate, up-to-date information about vaccines and immunizations.

Washakie Public Health Receives First SHARP SHOOTER Award

Washakie Public Health Nursing office in Worland, Wyoming accepted the first ever "SHARP SHOOTER" award in July for their efforts in protecting citizens in their county against vaccine-preventable diseases. Their office received a \$100 gift certificate to Office Depot for office supplies as part of the award. For your convenience, a "Sharp



Shooter" award application has been included with this issue of the Jab & Gab (INSERT). We hope you will consider submitting an application to share your immunization efforts, so we can continue to reward and share best practices in immunization with other providers in Wyoming.

* Cie Daniels, LPN (pictured to the left) presented this award as part of her last day as

an Outreach Specialist. She has resigned her position with WIP and is no longer part of the program. We wish Cie the best of luck in her future endeavors and appreciate her dedication and hard work for the Wyoming Department of Health over the past 15 years.

Wyoming Department of Health

JAB & GAB

Volume 4, Issue 8 August, 2008

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*Don't forget to check your email for communication from us!

FYI! The JAB & GAB is posted on the www.immunizewyoming.com website every month.

Vaccine Vaccine Vaccine Vaccine Vaccine



World of the Vaccine Office By Randy DeBerry

WyVIP Program Reducing Provider Inventory to a Two-Month Supply

Starting immediately, the WyVIP Program will be adjusting its ordering rules to comply with new CDC-issued guidelines. The CDC requires that grantees make every effort to have no more than an 8-week vaccine supply in their refrigerators and in the ordering process combined. These guidelines were instituted for the following reasons:

- To minimize wastage of program vaccine. This was brought to the Wyoming Immunization Program by Lewis Anderson, our CDC Program Officer, upon his site visit to Wyoming. Although Lewis was very pleased with the program, he mentioned that he was concerned about the vaccine levels in provider offices and the potential for wastage if a refrigerator malfunctioned.
- Nationally, the federal Vaccine for Children's program is facing funding issues. Please
 understand that the two-month supply rule is not just for Wyoming, but for every state/city
 participating in the Federal VFC program. These funding challenges are a direct result of the
 growth of the program, not only in the number of grantees, but also in the number of vaccines
 being supported by the Federal VFC program. As a result of this growth, the CDC needed to
 make a change in their vaccine supply recommendation from a 3-month supply to a 2-month
 supply to enable the program to continue to meet its mission requirement with its current level of
 available funding.

With this change in place, the importance of WyVIP providers notifying the program of extended vaccine needs via *Special Clinic Order Forms* has increased, as not only will you have less vaccine in your refrigerator but there will also be less supply available in the state for us to utilize. As such, please plan your special clinics accordingly and notify the program at least 1 month, preferably 6 weeks, in advance of extended vaccine needs so we can order appropriately.

Returning Vaccine Transfer Materials to Vaccine Program

Many of you have received boxes, cold packs, and/or thermometers from the Vaccine Program via vaccine transfers during the last month. As such, the question has come up as to how these materials should be returned to the Vaccine Program. If you have vaccine transfer supplies from the Vaccine Program, please return them via regular U.S. Mail. Your office/clinic will initially need to pay the cost of shipping the materials to the Vaccine Program. However, if you mail your receipt (not a copy but the original) to the Vaccine Program, we will process a refund check for you.

Shipping Labels for Returning Vaccine to McKesson

If you need shipping labels for returning expired vaccine to McKesson, they can be obtained from one of two places. First, all vaccine shipping boxes received from McKesson have a return shipping label already placed on top of the box. Please see the INSERT "Example of Return Shipping Label on McKesson Box". If you have a McKesson box, all you need to do is pack the vaccine, send a copy of the *McKesson Return Form* to the Vaccine Program, and send the box back. However, if you don't have a McKesson box, you can contact the Vaccine Program as we have prepaid UPS shipping labels for returning vaccine to McKesson. We would be glad to send your office a shipping label at your request.

If you have any questions regarding any of this information, please let us know. Thank You! Randy DeBerry, Vaccine Program Manager, (307) 777-8983.

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Education Education Education Education

August is National Immunization Awareness Month! by Andrea Clement-Johnson

August is a time to recognize that immunization is essential across the life span! People of all ages, communities, and professions need immunization as a part of their overall health and wellness. As part of promoting this effort, we have compiled materials that you may copy and display within your offices, or provide to your patients. These materials include:

- Materials for parents about the safety and importance of childhood immunizations
- * Materials promoting adolescent immunization
- * Materials promoting adult immunization
- * Materials promoting immunization for healthcare workers

We hope you find August a time to be reminded of the importance of immunization as part of improving the overall health of your patients and as a regular practice within your offices. We look forward to your promotion of this effort throughout the year, as well. If you would like more of these or additional materials we supply, you may access our materials request form at www.immunizewyoming.com, or call Andrea at (307) 777-8981, for specific materials needs or requests. We thank you for all you do to keep Wyoming healthy!

Medicare Part D Reimbursement Program for Adult Vaccines by Andrea Clement-Johnson

Although WyVIP is primarily a children's vaccine program, we recently learned about a tool that may be of use to private provider offices who supply adult vaccines to senior adults.

It is recognized that **reimbursement** and billing related to Part D vaccine claims can be challenging for providers who offer Zoster, and potentially other vaccines to adult patients. The *eDispense Part D Vaccine Manager* system may assist in alleviating some of these challenges.

The eDispense web-portal system can give providers the ability to:

- * Check patients' Medicare, Part D eligibility, and Part D vaccine coverage
- Provide out-of-pocket cost amounts to patients and access to Part D reimbursement amounts to licensed prescribers for vaccine product charges
- Submit vaccine product and administration fee claims to Medicare Part D plans
- Receive reimbursement from Medicare Part D plans for vaccine product and administration fee charges at plans' allowable reimbursement rates
- Generate hard-copy records for patients and for the practice

eDispense requires a one-time enrollment agreement from provider offices. The system is a secure web-portal created and administered by Dispensing Solutions, Inc. For information about the company or this program, please call them at 1-866-522-3386.

Upcoming Events & Trainings in Health and Immunization by Andrea Clement-Johnson

August 12-14 National Conference on Health Communication, Marketing, and Media Location: Atlanta, Georgia Website: http://www.cdc.gov/HealthMarketing/conference2008.htm

August 20 WIP Monthly Teleconference: 12:15 p.m.-1:30pm. Call in 1-877-278-8686, Participant ID, 687555

August 21 Policy Update for new enrollees or staff in need of updates. 8:00-9:00, please call Andrea by August 20 to RSVP and to receive call in information if you are interested in participating. **(307) 777-8981**

August 28 Immunization Update 2008. 10:00-12:00pm, An annual update from CDC, highlighting current and late-breaking immunization issues. Webcast available at http://www.cdc.gov/vaccines/ed/broadcasts.htm

September 17-19 Wyoming Public Health Association Annual Education Conference Best Western Ramkota, Casper, Wyoming. Website: http://wyopha.org/

Continuous Effectively Addressing Parents' Concerns about Immunizations

Web recast is available at http://www.cdc.gov/vaccines/ed/ciinc/2008June.htm Continuing Education credits available.

Continuous Adolescent Immunization: A focus on the Next Generation Featuring Joseph Domachowske, MD and Thad Wilson, APRN, PhD. Web recast available at http://adolimmondemand08.haymarketmedical.com or by phone teleconference at **1-888-696-0738**. Customer service support available at **1-866-330-7335**.

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Clinical Clinical Clinical Clinical Clinical

Clinical Corner By Joanna Briggs, RN



FDA Approves New DTaP-IPV Vaccine (KINRIX) For Children Ages 4-6 Years

On June 24, FDA approved the use of GlaxoSmithKline's Kinrix diphtheria tetanus toxoids, acellular pertussis adsorbed, and inactivated polio vaccine in children ages 4-6 years.

According to FDA's Product Approval Information, Kinrix vaccine is indicated for active immunization against diphtheria, tetanus, pertussis, and poliomyelitis as the **fifth** dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the **fourth** dose in the inactivated poliovirus vaccine (IPV) series in children **4 through 6 years of age** whose previous DTaP vaccine doses have been with INFANRIX and/or PEDIARIX for the first three doses and INFANRIX for the fourth dose.

More information, including package inserts, on Kinrix and other newly approved vaccines is available at: http://www.fda.gov/cber/

Preliminary Data Indicate 2007-08 Rotavirus Season was Less Severe Than Usual; New Vaccine May Have Played a Part

CDC published "Delayed Onset and Diminished Magnitude of Rotavirus Activity--United States, November 2007-May 2008" in the June 27 issue of MMWR. This and other MMWRs are available at: http://www.cdc.gov/mmwr/

The rotavirus activity through May 3, of the current season, as complied by the National Respiratory and Enteric Virus Surveillance System (NREVSS) and the New Vaccine Surveillance Network (NVSN), indicated that, when compared with the 15 previous seasons (spanning 1991-2006), rotavirus activity during the current season appeared to have a delayed onset of 2-4 months and diminished in magnitude by greater than 50%. Additional surveillance and epidemiologic studies are needed to confirm the impact of rotavirus vaccination on the current 2007-08 season. We also hope to show the impact of the rotavirus vaccine on the incidence and epidemiology of rotavirus during future seasons.

Influenza Activity

On June 27th, the CDC published MMWR "Influenza Activity--United States and Worldwide, 2007-08 Season". During the 2007-08 influenza season, influenza activity peaked in mid-February in the United States and was associated with greater mortality and higher rates of hospitalization of children ages 0-4 years, compared with each of the previous three seasons. In the United States, influenza A (H1N1) was the predominant strain early in the season; influenza A (H3N2) virus increased in circulation in January and predominated overall. While influenza A (H1N1), A (H3N2), and B viruses co circulated worldwide, influenza A (H1N1) virus was most commonly reported in Canada, Europe, and Africa, and influenza B viruses were predominant in most Asian countries. This report summarizes influenza activity in the United States and worldwide during the 2007-08 influenza season (September 30, 2007-May 17,2008).

Influenza-Related Pediatric Mortality

As of June 19, 2008, 83 deaths associated with influenza infections which occurred among children less than 18 years of age during the 2007-08 influenza season were reported to CDC. Wyoming did not experience any of these deaths in children. The expanded ACIP recommendation is enclosed (INSERTS). Additional information is available at http://www.cdc.gov/flu.

It is not too early to be addressing influenza and what needs to be done this year. Be creative in getting the public vaccinated! Also, the new Flu VISs for 2008-09 are included (INSERTS).

Vaccine Safety Monitoring: Vaccine Adverse Event Reporting System (VAERS)

General Description of VAERS and the CISA Network

The Vaccine Adverse Event Reporting System (VAERS) is part of a larger system that helps to make sure vaccines are safe and work as intended. VAERS is managed by CDC and FDA. To ensure vaccines are safe, vaccines are developed in accordance with the highest standards of safety. FDA requires extensive safety testing before a vaccine is licensed and distributed to the public. After licensing, VAERS is used to continually monitor vaccines for safety and efficacy.

VAERS receives reports of many events that occur after immunization. Some of these events may occur coincidentally following vaccination, while others may truly be caused by vaccination. It is important to remember that many adverse events reported to VAERS may not be caused by vaccines.

Continued on next page —>

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Clinical WylR WylR WylR WylR

More in depth studies are usually required to investigate the association between a vaccine and an adverse event. Since 1990, most of the reported adverse events describe mild side effects such as fever and rash. Through continued monitoring, VAERS helps to ensure that the benefits of vaccines are far greater than the risks. More information about VAERS can be found at http://www.cdc.gov/vaccinesafety/vaers/.

The Clinical Immunization Safety Assessment (CISA) Network was established in 2001 as a collaborative project between CDC's Immunization Safety Office (ISO) and six medical research centers. CISA studies the pathophysiologic basis of adverse events after immunization, studies risk factors (including genetic) associated with developing an adverse event after immunization (AEFI), and provides clinicians with evidence-based guidelines when considering immunization of those at risk for AEFIs. CISA is uniquely suited to study post-licensure vaccine safety in special populations due to its clinical access to both the special populations and the specialists who care for them. More information about CISA can be found at http://www.cdc.gov/vaccinesafety/cisa/.

Please see the **INSERTS** for "VAERS Talking Points", which discusses HPV disease, Gardasil, and VAERS reports associated with the Gardasil vaccine.



Get WylR'd! by John Anderson

Version Upgrade (V4.3.1.2)

We have finally finished the testing process for the latest version upgrade and have scheduled an upgrade for the end of July. While there were still a few bugs identified in the process, we believe that these were minor in comparison to the upgrade functionality that will be available, as well as scripts that will fix current outstanding system bugs. Some changes that you may experience:

- * Add Anonymous Patients
- * Opting Patient Out & Opting Patient Back In
- * Decline Ownership
- Displaying Patient Age on Vaccine Summary
- Breaking out DtaP, Tdap, Td family in detail on Patient Record Summary
- * Requirement of Lot Number when Inputting Administered Vaccine

These changes will be posted on our website within our updated User Manual. As always, feel free to contact us with any questions you may have regarding these improvements. We are not the first State to move to this version, so the number of system bugs that we experience will most likely be less than the other early adopters (unlike the last upgrade).

As for the next targeted version (V4.4), we are still working on getting a secure certificate for our test environment so that it can be housed on a server based environment. Again, this configuration change will allow us to login remotely to access the system to see if things behave differently than on a desktop environment. V4.4 is undergoing the review of the same test scripts that STC goes through prior to release. As previously mentioned, we are working towards acquiring a secure server site for our test environment as well. Please, let us know if you would like to participate in this testing process – you may learn more about the WyIR than you ever wanted to know!

Revival Contract – new functionalities pending...

Our contract with our software vendor is in the process of getting renewed, and we have found a partner in Public Health and Emergency Preparedness Program (PHEP) to help pay for some functionalities that we would not have been able to afford otherwise. Much thanks to PHEP for the financing to improve the functionality of the WyIR. Of the new functionalities available to the WyIR in the new contract:

• Mass Immunizations Stand Alone. While we detail how to have an electronic searchable "backup file" of immunization records in the WylR User Guide, we realize that this will not necessarily assist in the data collection in the event of a bio-terror attack or pandemic flu outbreak. This thumb drive application will allow the remote collection of an immunization event if internet access is not available at the time of vaccine administration. Once populated, the end user simply uploads the data to the WylR, where it will then undergo a deduplication process to ensure accuracy of imported data. This tool gives us more flexibility to respond appropriately in the event of an emergency situation.

Continued on the next page —>

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- Management Reports Module GIS capabilities. One of the twelve functional standards of an immunization
 registry is the ability to produce detailed geographic reports. Until now, we have been amiss of this standard due to
 monetary constraints. With assistance from the PHEP, we have acquired the ability to produce Geographic
 Information Systems level mapping regarding numerous variables by area, such as immunization rates, expiring
 vaccines, etc.... We are excited regarding this new functionality, and look forward to presenting it to you in the very
 near future.
- Completion of Interface Development. With the Revival Contract in place, we eagerly await the completion of interface development for the seven participating offices. We will let all know about the outcome once complete. Also, we will continually look for other funding sources to assist in interface development from other interested parties. If your office currently has an Electronic Medical Record (EMR) System, and is using the WyIR, and would like to not to do duplicate data entry, please contact us and let us know you are interested. We will place you on a waiting list to move forward once additional funding is acquired.

Laptops for WylR Users

We are working with the Department of Health IT program to retrofit some laptops with improved memory so that we may be able to loan them to users of the WylR to enhance the clinical flow for their patients. We hope that these upgrades will continue to enhance the efficiency of vaccination delivery for your office. Ideally, they would be in the room with each patient to research their history on the WylR in order to produce an accurate forecast prior to administration of vaccine, as well as immediately enter data for the patient receiving a vaccination. We already have a couple of names on the waiting list, so if your office would like to take advantage of this opportunity, please do not hesitate to contact us at your convenience. John Anderson (307) 777-5773.

Get trained on the WylR from your desktop...

Please navigate to the WyIR section within www.immunizewyoming.com – there, you will see our Distance Learning Tools posted for you to utilize at your convenience. This format allows all new users to receive training prior to receiving administrative rights to the WyIR. It also allows current users to refresh their abilities as well. Please keep in mind that once our proposed Confidentiality and Security Polices and Procedures are approved, all new users will have to sign a form denoting that they viewed and completed the Distance Learning Training tool that corresponds to their requested access level. Please, take a look at them and let us know what you think.

Updated System Bugs posted

As new bugs are identified, we will notify the primary WyIR contact at each office of the information. It is indeed nice to have updated primary contact information from the WyIR Enrollment Process for a purpose such as this. Please navigate to the link available within the WyIR section on the www.immunizewyoming.com webpage to see the latest system bugs for Version 4.3.1.2.

WyIR Password Requirements

Please see the **INSERTS** for important information regarding password requirements for WylR users.



WylR Room by Lisa Wordeman

The summer has flown by and we are planning for our back-to-school vaccines. Our WylR users have an advantage in that they have access to great tools, such as *Reminder Recall* and the official *School Form*.

The Reminder Recall is beneficial, not just in helping to increase your rates, but by helping you identify the kids in your clinic who will be needing vaccines before school starts. This will allow you to remind parents to bring their kids in to your clinic and also help you to prepare for their vaccine needs. Once the patient receives the necessary vaccine, you may print out the *School Form* and the parent can pass it along to the School Nurse. These are great tools to use to keep everything running as smooth as possible in such a hectic time of year.

Don't forget to call our Help Desk at **1-800-599-9754** if you have any questions about the Registry—I'm here to help!

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Top Vaccines Administered by WylR Users in June 2008

Vaccine Type	# of Doses	% of Total
Pneumococcal(PCV7)	1334	12.07%
Hib	1046	9.45%
DTaP/Hep B/IPV	864	7.82%
Varicella	815	7.38%
Hep A- Ped/Adol	783	7.09%
DTaP	773	7%
HPV, quadrivalent	641	5.8%
MMR	622	5.63%
Rotavirus	584	5.28%
Tdap	482	4.36%



Shining Stars! By Lily Valdez

WyVIP congratulates the following providers for submitting their June reports correctly and by the 2nd business day of July. I appreciate your hard work and efforts in helping this Incentive program become a huge success. You all did an awesome job!

ABC Pediatrics Albany Co PHN Banner Medical Clinic Bennett, Michele L., MD, PC Big Horn Basin Childrens Clinic Big Horn Co PHN-Greybull Big Horn Co PHN-Lovell Campbell Co Memorial Hospital Campbell Co PHN Carbon Co PHN-Rawlins Carbon Co PHN-Saratoga Casper Natrona Co Health Dept Cedar Hills Family Clinic Cheyenne Children's Clinic City Co Health Dept - Chevenne Converse Co PHN Crook Co PHN Ellbogen, David A., MD Emerg-A-Care Engle, Deeanne, MD Evanston Regional Hospital Fremont Co PHN-Riverton Fremont Family Practice FT Washakie Health Center Goshen Co PHN Green, Richard D., MD Health Care for the Homeless

Hot Springs Co PHN Hunter Family Medical Clinic, PC Ivinson Memorial Hospital, Nursery Jackson Pediatrics Johnson Co PHN

Kurt S. Johnson, MD, PC Lander Medical Clinic Lander Regional Hospital Lincoln Co PHN-Afton Lincoln Co PHN- Kemmerer Mountain View Medical Center Niobrara Co PHN

North Big Horn Hospital - Clinic Northeast Wyoming Pediatrics

Park Co PHN-Powell Platte Co PHN

Platte Valley Medical Clinic

Region V Boces

Rock Springs Family Practice, Inc Sheridan Co Comm. Health Sheridan Memorial Hospital South Lincoln Medical Center South Sheridan Medical Center Star Valley Medical Center

Sublette Co PHN

Sublette Co RHC - Big Piney Sublette Co RHC - Pinedale

Sweetwater Co Comm. Nursing Svcs-Green

River

Sweetwater Co Comm. Nursing Svcs-Rock

Springs Teton Co PHN

Thayne Family Medical Clinic Thomas, Jennifer, MD, PC Uinta Co PHN-Evanston Uinta Co PHN-Lyman **Uinta Family Practice UW Family Practice** Wagon Circle Medical Clinic Washakie Co PHN Weston Co PHN

Willow Creek Family Medicine Women's Health Center Woodward, Drew, MD, PC Wyoming Health Initiative

By submitting their monthly reports correctly and by the 2nd business day of the month for three months the following providers have achieved the Good Job! Award (stress ball push pen).

Kinbrook, Michelle, MD Oregon Trail Rural Health Clinic Sweetwater Medical Group

The following providers have submitted their monthly reports correctly and by the 2nd business day of the month for six months and have achieved the Excellent! Award (happy highlighter).

Alpha Family Medicine Alpine Family Medical Clinic

Babson & Associates of Primary Care

Big Horn Pediatrics Billings Clinic - Cody

Bridger Valley Family Practice

Brown, Craig, MD

Castle Rock Medical Center Cheyenne Family Medicine

Cheyenne Health & Wellness Center Community Health Center of Central Wyo-

mina

Evanston Pediatrics Family Care Clinic, LLC Family Medical Care Family Medical Center Fisher, Carol A., MD Fremont Co Pediatric Clinic Goose Creek Pediatrics Granum, Michael J., MD Laramie Childrens Clinic Laramie Pediatrics

Memorial Hospital of Carbon Co. Memorial Hospital of Sweetwater Co.

Moorcroft Clinic Myers, Harlen, MD

Pediatric and Adolescent Clinic, Inc.

Platte Co Memorial Hospital

Pockat, Tom, MD

Quinn, Michael J., MD-FAAP Rawlins Family Medical Red Rock Family Practice

Riverton Community Health Center

South Lincoln Medical Clinic St. John's Medical Center Star Valley Family Physicians Sweetwater Pediatrics, PC The Family Clinic, LLC Total Family Health, PC Tri-County Medical Center

UW Student Health Western Family Care

Western Medical Associates, LLC

Wind River Pediatrics

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Sun	Mon	Tue	Wed	Thu	Fri	Sat
AUGUST	IS NATIONAL	IMMUNIZATION	AWARENESS	MONTH!	1	2
3	4 Monthly Reports Due	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20 WIP Tele- conference	21 WIP Policy Training	22	23
24	25	26	27	28	29	30

Important Dates in August

August 4: ALL monthly reports due:

- Doses Administered Forms
- Inventory Forms
- Temperature Logs
- A REMINDER! The Doses Administered Reports you send in are the basis for replenishing your vaccine orders. If you have Special Clinic Order forms, flu doses administered, transfer of vaccine forms and/or preference forms, please send them at this time as well.

August 20: WIP Monthly Teleconference: 12:15 p.m.-1:30pm. Call in information 1-877-278-8686, Participant ID, 687555.

August 21: WIP Policy and Procedure Training, Please RSVP to Andrea by August 20 for call in information if interested in participating.

Some important reminders about WyVIP:

- The maximum administrative fee your office may charge for WyVIP vaccine is \$14.31 per shot.
- Vaccine nearing expiration must be reported to our office within 60 days of expiration.
- An up-to-date emergency plan for relocating vaccine in the event of power failures must be available in your offices.
- A primary and **secondary** immunization staff contact are necessary for each office.
- All Vaccine Information Statements (VIS) must be given PRIOR to administration of any vaccine.
- Please read the WyVIP policy packet and other available policies and procedures posted at www.immunizewyoming.com

It's federal law!

You must give your patients current Vaccine Information Statements (VISs)

This article was written by Neal A. Halsey, MD, director, Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health and was last updated by the Immunization Action Coalition in June 2008.

As healthcare professionals understand, the risks of serious consequences following vaccination are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccine recipients (or the parents/legal representatives of minors) with objective information on vaccine safety and the diseases that the vaccines protect against, so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in healthcare providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

What are VISs?

VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccine recipient or the minor child's parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should answer questions and address concerns that the recipient or the parent/legal representative may have.

Use of the VIS is mandatory!

Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult recipient or to the child's parent/legal representative.

VISs are also available for pneumococcal polysaccharide vaccine, as well as various vaccines used primarily for international travelers. The use of these VISs is recommended but not currently required by federal law.

An alternative VIS—the multi-vaccine VIS—is an option to providing single-vaccine VISs when administering one or more of these routine birth-through-6-month vaccines: DTaP, hepatitis B, Hib, pneumococcal (PCV), polio (IPV), or rotavirus. The multi-vaccine VIS can also be used when giving combination birth-through-6-month vaccines (i.e., Pediarix or Comvax) or when giving two or more routine birth-through-6-month vaccines together at other pediatric visits (e.g., 12–15 months or 4–6 years).

State or local health departments or individual providers may place the clinic name on the VISs, but any other changes must be approved by the director of CDC's National Center for Immunization and Respiratory Diseases.

What to do with VISs

Some of the legal requirements concerning the use of VISs are as follows:

- Before an NCVIA-covered vaccine is administered to anyone (this includes adults!), you must give the patient or the parent/legal representative a copy of the most current VIS available for that vaccine. Make sure you give your patient time to read the VIS prior to the administration of the vaccine.
- 2. You must record in your patient's chart the date the VIS was given.
- You must also record on the patient's chart the publication date of the VIS, which appears on the bottom of the VIS.

How to get VISs

VISs can be downloaded from the Immunization Action Coalition's website at www.immunize. org/vis or CDC's website at www.cdc.gov/vaccines/pubs/vis/default.htm. Ready-to-copy ver-

To obtain a complete set of current VISs in more than 30 languages, visit IAC's website at www.immunize.org/vis

sions may also be available from your state or local health department.

Foreign language versions of VISs are not officially available from the CDC; however, several state health departments have arranged for their translations. These versions do not require CDC approval. You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis. To find VISs in alternative formats (e.g., audio, web-video), go to: www.immunize.org/vis/vis_audio.asp.

Most current versions of VISs

As of June 2008, the most recent versions of the VISs are as follows:

DTaP/DT/DTP 5/17/07	PCV 9/30/02
hepatitis A 3/21/06	PPV 7/29/97
hepatitis B 7/18/07	polio 1/1/00
HPV (H. papillomavirus) 2/2/07	rabies 1/12/06
Hib 12/16/98	rotavirus 4/12/06
influenza (LAIV) 10/4/07	shingles 9/11/06
influenza (TIV) 7/16/07	Td 6/10/94
Japan. enceph 5/11/05	Tdap 7/12/06
meningococcal 1/28/08	typhoid 5/19/04
MMR 3/13/08	varicella 3/13/08
vellow fever	11/9/04

"We have an obligation to provide patients and/or parents with information that includes both the benefits and the risks of vaccines. This can be done with the Vaccine Information Statements that healthcare providers are required by law to provide prior to the administration of vaccines."

Walter A. Orenstein, MD, past director, National Immunization Program, CDC

www.immunize.org/catg.d/p2027.pdf • Item #P2027 (6/08)

INACTIVATED VACCINE WHAT YOU NEED TO KNOW 2008-09

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 Why get vaccinated?

Influenza ("flu") is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Other illnesses can have the same symptoms and are often mistaken for influenza. But only an illness caused by the influenza virus is really influenza.

Anyone can get influenza, but rates of infection are highest among children. For most people, it lasts only a few days. It can cause:

- · fever · sore throat · chills · fatigue
- · cough · headache · muscle aches

Some people get much sicker. Influenza can lead to pneumonia and can be dangerous for people with heart or breathing conditions. It can cause high fever, diarrhea and seizures in children. On average, 226,000 people are hospitalized every year because of influenza and 36,000 die – mostly elderly.

Influenza vaccine can prevent influenza.

2 | Inactivated influenza vaccine

There are two types of influenza vaccine:

1. Inactivated (killed) vaccine, or the "flu shot" is given by injection into the muscle. 2. Live, attenuated (weakened) influenza vaccine is sprayed into the nostrils. This vaccine is described in a separate Vaccine Information Statement.

Influenza viruses are always changing. Because of this, influenza vaccines are updated every year, and an annual vaccination is recommended.

Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. When there is a close match the vaccine protects most people from serious influenzarelated illness. But even when the there is not a close match, the vaccine provides some protection. Influenza vaccine will *not* prevent "influenza-like" illnesses caused by other viruses.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts up to a year.

Some inactivated influenza vaccine contains a preservative called thimerosal. Some people have suggested that thimerosal may be related to developmental problems in children. In 2004 the Institute of Medicine reviewed many studies looking into this theory and concluded that there is no evidence of such a relationship. Thimerosal-free influenza vaccine is available.

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Who should get inactivated influenza vaccine?

All children 6 months and older and all older adults:

- All children from 6 months through 18 years of age.
- Anyone 50 years of age or older.

Anyone who is at risk of complications from influenza, or more likely to require medical care:

- Women who will be **pregnant** during influenza season.
- Anyone with long-term health problems with:
 - heart disease kidney disease liver disease
 - lung disease metabolic disease, such as diabetes
- asthma anemia, and other blood disorders
- Anyone with a weakened immune system due to:
 - HIV/AIDS or other diseases affecting the immune system
- long-term treatment with drugs such as steroids
- cancer treatment with x-rays or drugs
- Anyone with certain **muscle or nerve disorders** (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone 6 months through 18 years of age on **long-term aspirin treatment** (they could develop Reye Syndrome if they got influenza).
- Residents of nursing homes and other chronic-care facilities.

Anyone who lives with or cares for people at high risk for influenza-related complications:

- Health care providers.
- Household contacts and caregivers of children from birth up to 5 years of age.
- Household contacts and caregivers of
 - people 50 years and older, or
 - anyone with medical conditions that put them at higher risk for severe complications from influenza.

Health care providers may also recommend a yearly influenza vaccination for:

- People who provide essential community services.
- People living in **dormitories**, **correctional facilities**, or under other **crowded conditions**, to prevent outbreaks.
- People at high risk of influenza complications who travel to the Southern hemisphere between April and September, or to the tropics or in organized tourist groups at any time.

Influenza vaccine is also recommended for anyone who wants to reduce the likelihood of becoming ill with influenza or spreading influenza to others.



When should I get influenza vaccine?

Plan to get influenza vaccine in October or November if you can. But getting vaccinated in December, or even later, will still be beneficial in most years. You can get the vaccine as soon as it is available, and for as long as illness is occurring in your community. Influenza can occur any time from November through May, but it most often peaks in January or February.

Most people need one dose of influenza vaccine each year. Children younger than 9 years of age getting influenza vaccine for the first time – or who got influenza vaccine for the first time last season but got only one dose – should get 2 doses, at least 4 weeks apart, to be protected.

Influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

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Some people should talk with a doctor before getting influenza vaccine

Some people should not get inactivated influenza vaccine or should wait before getting it.

- Tell your doctor if you have any **severe** (life-threatening) allergies. Allergic reactions to influenza vaccine are rare.
 - Influenza vaccine virus is grown in eggs. People with a severe egg allergy should not get the vaccine.
 - A severe allergy to any vaccine component is also a reason to not get the vaccine.
 - If you have had a severe reaction after a previous dose of influenza vaccine, tell your doctor.
- Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). You may be able to get the vaccine, but your doctor should help you make the decision.
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor or nurse about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.



What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:

- soreness, redness, or swelling where the shot was given
- fever aches

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Vaccine Information Statement Inactivated Influenza Vaccine (7/24/08) 42 U.S.C. §300aa-26

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, a type of influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

7

What if there is a severe reaction?

What should I look for?

 Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.



The National Vaccine Injury Compensation Program

A federal program exists to help pay for the care of anyone who has a serious reaction to a vaccine.

For more information about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

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How can I learn more?

- Ask your immunization provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO)
 - Visit CDC's website at www.cdc.gov/flu





INFLUENZAVACCINE WHAT YOU NEED TO KNOW 2008-09

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Influenza vaccine can prevent influenza.

2 Live

Live, attenuated influenza vaccine - LAIV (nasal spray)

There are two types of influenza vaccine:

1. Live, attenuated influenza vaccine (LAIV) contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils. 2. Inactivated influenza vaccine, sometimes called the "flu shot," is given by injection. Inactivated influenza vaccine is described in a separate Vaccine Information Statement.

Influenza viruses are always changing. Because of this, influenza vaccines are updated every year, and an annual vaccination is recommended.

Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. When there is a close match the vaccine protects most people from serious influenza-related illness. But even when the there is not a close match, the vaccine provides some protection. Influenza vaccine will *not* prevent "influenza-like" illnesses caused by other viruses.

It takes up to 2 weeks for protection to develop after the vaccination. Protection lasts up to a year.

LAIV does not contain thimerosal or other preservatives.

$ig(m{3}\mid \mathsf{Who}\ \mathsf{can}\ \mathsf{get}\ \mathsf{LAIV}?$

LAIV is approved for **people from 2 through 49 years of age**, who are not pregnant and do not have certain health conditions (see #4, below). Influenza vaccination is recommended for people who can spread influenza to others at high risk, such as:

- Household contacts and out-of-home caregivers of children up to 5 years of age, and people 50 and older.
- Physicians and nurses, and family members or anyone else in close contact with people at risk of serious influenza.

Health care providers may also recommend a yearly influenza vaccination for:

- People who provide essential community services.
- People living in **dormitories**, **correctional facilities**, or under other crowded conditions, to prevent outbreaks.

Influenza vaccine is also recommended for anyone who wants to reduce the likelihood of becoming ill with influenza or spreading influenza to others.

4 Some people should *not* get LAIV

LAIV is not licensed for everyone. The following people should get the **inactivated** vaccine (flu shot) instead:

- Adults 50 years of age and older or children between 6 months and 2 years of age. (Children younger than 6 months should not get *either* influenza vaccine.)
- Children younger than 5 with asthma or one or more episodes of **wheezing** within the past year.
- People who have long-term health problems with:
 - heart disease kidney or liver disease
 - lung disease metabolic disease, such as diabetes
 - asthma anemia, and other blood disorders
- Anyone with certain **muscle or nerve disorders** (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone with a weakened immune system.
- Children or adolescents on long-term aspirin treatment.
- Pregnant women.

Tell your doctor if you ever had **Guillain-Barré syndrome** (a severe paralytic illness also called GBS). You may be able to get the vaccine, but your doctor should help you make the decision.

The flu shot is preferred for people (including health-care workers, and family members) in close contact with anyone

who has a severely weakened immune system (requiring care in a protected environment, such as a bone marrow transplant unit). People in close contact with those whose immune systems are less severely weakened (including those with HIV) may get LAIV.

Anyone with a **nasal condition** serious enough to make breathing difficult, such as a very stuffy nose, should get the flu shot instead.

Some people should talk with a doctor before getting *either* influenza vaccine:

- Anyone who has ever had a <u>serious</u> allergic reaction to <u>eggs</u> or another vaccine component, or to a <u>previous</u> dose of influenza vaccine. LAIV also contains MSG, arginine, gentamicin, and gelatin.
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor or nurse about whether to reschedule the vaccination. People with a **mild illness** can usually get the vaccine.

When should I get influenza vaccine?

Plan to get influenza vaccine in October or November if you can. But getting it in December, or even later, will still be beneficial most years. You can get the vaccine as soon as it is available, and for as long as illness is occurring in your community. Influenza can occur from November through May, but it most often peaks in January or February.

Most people need one dose of influenza vaccine each year. Children younger than 9 years of age getting influenza vaccine for the first time – or who got influenza vaccine for the first time last season but got only one dose – should get 2 doses, at least 4 weeks apart, to be protected.

LAIV may be given at the same time as other vaccines.

What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine *can* cause mild symptoms in people who get it (see below).

Mild problems:

Some children and adolescents 2-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

These symptoms did not last long and went away on their own. Although they can occur after vaccination, they may

not have been caused by the vaccine.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.
- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Millions of doses of LAIV have been distributed since it was licensed, and no serious problems have been identified. Like all vaccines, LAIV will continue to be monitored for unusual or severe problems.

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What should I do?

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement

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